REMARKS

Claims 1-53 are pending. The Examiner has stated that claims 22-31 and 49-52 are withdrawn from consideration and that claims 1-21, 31-48, and 53 are rejected. It is noted that claim 31 is listed both as having been withdrawn and as having been rejected. With reference to the Response to the Restriction Requirement (dated March 3, 2003), Applicants submit that only claims 22-30 should have been withdrawn, and claim 31 should not be withdrawn. Thus, Applicants herewith cancel claims 22-30 and 49-52.

Summary of the Invention of the Present Application:

The invention of the present application provides a composition including the tannate salts of phenylephrine and pyrilamine as active pharmaceutical ingredients. The method of obtaining the composition involves a conversion process, which comprises the steps of mixing a dispersing agent and tannic acid in a suitable solvent to generate a mixture in liquid form. A solution of phenylephrine and pyrilamine as salts or in the free base form dissolved in a solvent, is added slowly to the dispersing agent/tannic acid mixture to generate the tannate salt. The resulting tannate salts of phenylephrine and pyrilamine are then subsequently processed into suitable dosage forms, such as a suspension or tablets. The presence of the dispersing agent prevents the clumping and aggregation of the tannate salt formed. As a result, the presence of a

dispersing agent aids in ameliorating the problem described in the application of pharmaceutical compositions that contain variable, and sometimes sub-therapeutic, levels of active pharmaceutical ingredients. Since the tannate salts of phenylephrine and/or pyrilamine are generated and incorporated in-situ into the dosage form during the manufacturing process, the purification and drying steps, which are generally required for the isolation of the tannate salts, are eliminated.

To provide the composition in a suspension, the dispersion of the tannate salts in the solvent obtained from the conversion process is transferred to a suitable liquid medium, which includes co-solvents, preservatives, sweetening/flavoring, pH adjusting agents, coloring agents, thickening agents and anti-caking agents. The resulting mixture is then processed into suitable liquid dosage forms. Alternatively, the composition may be provided in tablet form. In this method, the tannate salts in the solvent obtained from the conversion process are mixed with a diluent and dry binding/matrix forming agents, and are wet granulated by spraying with a binder solution. The granulation is subsequently dried and then is dry blended with more diluent, sweetening agents, hardness increasing agents, coloring agents and flavoring agents as necessary. The resulting granulate can be processed into tablets.

Claim Rejections 35 U.S.C. § 112:

The Examiner has rejected claims 1-21, 31-48 and 53 under 35 U.S.C. §

112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regard as the invention. In particular, the Examiner has stated that it is not clear to what the "first solvent", recited in claims 1, 31, and 53, refers. Additionally, the Examiner states that it is not clear how the "first solvent" differs from the "second solvent."

In response, Applicants assert that the first solvent and the second solvent are two separate elements for the purpose of the claim but might be the same material or composition, such as water. Support for this assertion may be found in the specification at least at page 7, lines 1-3. Applicants submit that various solvents, such as water, would be readily recognized by those having skill in the relevant art. Further, Applicants assert that the second solvent may also be water (see at least page 6, lines 5-6 of the specification). Although these solvents both may be the same substance, such as water, the terminology "first solvent" and "second solvent" are used to teach that two separate liquid mixtures are made with suitable solvents (one including tannic acid and one including the active pharmaceutical ingredients), and then those two mixtures are combined. In view of the above, Applicant respectfully requests a withdrawal of the rejection of claims 1-21, 31-48 and 53 under 35 U.S.C. § 112.

Claim Rejections 35 U.S.C. § 103:

The Examiner has rejected claims 1-21, 31-48 and 53 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,287,597 (Gordziel) in view of

U.S. Patent No. 5,599,846 (Chopdekar). Applicants respectfully disagree.

The Examiner has stated that Gordziel discloses a composition including tannate salts prepared by the conventional isopropanol route, and that Gordziel further discloses that antihistamines in the form of their tannate salts can be prepared alternatively by a water route. However, Applicants submit that preparation of such a composition simply by a water route is known in the art and, in fact, the particular water route disclosed in Gordziel was discussed by Applicants in the "Background" section of the present application. Applicants further submit that this water route is not that of the invention of the present application. In particular, Gordziel describes reacting the antihistamine/decongestant free bases (phenylephrine and pyrilamine) with tannic acid in the presence of a solvent, which in the water route would be water. However, the present invention is directed to a composition of tannate salts prepared via the particular route described in the application, which includes a separate step of preparing a dispersion, including a dispersing agent, which is then added to a solution including the decongestant and antihistamine. Gordziel does not disclose this step.

Apart from the route of preparation of the composition, the Examiner has further stated that the composition disclosed by Gordziel and the claimed composition are directed to the same composition. Again, Applicants disagree. The claims of the present application recite the composition as being made by the claimed process. Since Gordziel does not disclose this process, it cannot disclose the composition as claimed.

Applicants also note that the Examiner has stated that Gordziel does not

disclose the specific step of making the compositions including tannate salts by a water route, namely, reacting phenylephrine and pyrilamine with tannic acid in the presence of water. However, the Examiner states that such a route would have been obvious in view of Chopdekar, which the Examiner states teaches this method of preparation. However, Applicant asserts that the method taught by Chopdekar does not include a first dispersion, including a dispersing agent with tannic acid. By contrast, Applicants submit that the currently recited method for preparing the claimed composition, recites a "dispersing agent" in claims 1, 31 and 53. This dispersing agent prevents the clumping and aggregation of the tannate salt formed when the first solution is transferred to the first dispersion. The presence of a dispersing agent in the present invention aids in ameliorating the significant problem described in the application of pharmaceutical compositions that contain variable, and sometimes sub-therapeutic, levels of active pharmaceutical ingredients. Since Chopdekar does not teach or even suggest a dispersing agent in its described method, Applicants assert that the combination of the Gordziel and Chopdekar references do not teach all the limitations of independent claims 1, 31, and 53.

Further, as noted above with respect to Gordziel, Applicants also acknowledge that Chopdekar teaches a water route for preparation of compositions, but submit that Chopdekar, like Gordziel, only teaches the old water route discussed by Applicants in the background of the present application. In particular, Chopdekar simply describes contacting phenylephrine in its free base form with tannic acid in the

presence of water. However, the present invention is directed to a composition of tannate salts prepared via the particular route described in the application, which includes a separate step of preparing a dispersion, including a dispersing agent, which is then added to a solution including the decongestant and antihistamine. Chopdekar does not disclose this step. Thus, in reviewing Chopdekar, the person of ordinary skill in the art would only be taught the old method of preparation of these compositions. Additionally, since both Chopdekar and Gordziel each only teach the old water route, if one skilled in the art were to review the Chopdekar reference in combination with Gordziel, that combination would only teach a composition made by the old water route. Thus, it would not include solution and a separate dispersion including a dispersing agent. Thus, a person of ordinary skill making a composition as taught by Chopdekar would not achieve the substantial benefits of the process of the present application, (i.e., not having variance of API from batch to batch and aggregation of the tannate salts.

In addition, the Examiner states that (1) the specific water route, (2) the specific amounts of active or inactive ingredients, and (3) the specific pH of the composition of the application would have been obvious over Gordziel in view of the method of Chopdekar. As addressed above, the water route taught in both references is the old water route. There is no teaching of a separate dispersion including a dispersing agent in either reference. Thus even a combination of the two references does not teach all the limitations of the claims. Applicants further assert that the

Examiner's contention that the specific amounts of ingredients or pH of the composition would be obvious is unsupported in that these amounts are not taught by, nor suggested by, either reference. Further, the Examiner has said that the order of steps is prima facie obvious. Applicants assert that this statement also is unsupported, namely because the references, either alone or combined, do not teach every step of the process as recited in the claims. Finally, the Examiner states that optimization of amounts of ingredients in pH is considered "within the skill of the artisan, absent evidence to the contrary." Applicants submit that the Examiner has not satisfied his burden of establishing obviousness. This burden cannot be satisfied by announcing that a particular element is within the skill of the artisan unless the Applicant can demonstrate otherwise. Rather than meeting his burden of establishing obviousness, the Examiner has attempted to shift a burden of proving nonobviousness to the Applicant. This is clearly improper under § 103.

In view of the above, Applicants respectfully request a withdrawal of the rejection of claims 1-21, 31-48, and 53 under 35 U.S.C. §103.

Conclusion:

For the foregoing reasons, it is submitted that all claims are patentable and a Notice of Allowance is respectfully requested.

Please charge $55.00 to Deposit Account No. 23-3000, which represents

the fee for a one-month extension of time. If any additional fee or surcharges are deemed due, please charge same.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

By: _____
David E. Jeffries, Reg. No. 46,800

Wood, Herron & Evans, L.L.P.
2700 Carew Tower
Cincinnati, OH 45202
(513) 241-2324 (voice)
(513) 421-7269 (facsimile)
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